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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,015	05/15/2002	Masayoshi Maki	56687(71526)	7186
21874	7590	06/29/2004	EXAMINER	
EDWARDS & ANGELL, LLP			FUBARA, BLESSING M	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1615

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,015	Applicant(s) MAKI ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time; certified translation of JP 11187415, amendment and remarks filed 03/01/04. Claims 1-3 and 5 are pending.

Priority

1. Receipt is acknowledged of translation of papers for the JP 11/187415 submitted on 03/01/04 under 35 U.S.C. 119(a)-(d) and the submission of the translation is now in accordance with 37 CFR 1.55 and satisfies the requirement of 35 USC 119(a)-(d). Therefore, the rejection of the claims over EP 0 976 405 no longer stands. See MPEP § 201.15.
2. Instant claim 1 is amended to recite estradiol in an amount of not more than 2% by weight of the total base. In light of this amendment, the rejections of claims 1-3 as being anticipated by Yamanaka et al. (US 5,176,916) and claims 1-5 and 5 as being anticipated by Oda et al. (US 5,725,874) do not hold anymore. A new rejection follows below.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirano et al. (US 5,820,878).

Hirano discloses a percutaneous adhesive patch (abstract; column 2, line 12; column 3, lines 54, 62 and 63) and the adhesive patch comprises softening agents such as liquid paraffin, polybutene, castor oil, cottonseed oil, palm oil, coconut oil and process oil (column 2, lines 58-60). The patch further comprises additives such as tackifiers and the tackifiers that can be included in the patch preparation are saturated alicyclic hydrocarbon resins, rosin esters, alicyclic hydrocarbons, terpene hydrogenated resins and hydrogenated rosin esters (column 3, lines 22-29). The patch contains at least two hormones, estrogen and luteal hormones with estradiol as the preferred estrogen and luteal hormones selected from the group consisting of progesterone, hydroxyprogesterone caproate, medroxyprogesterone acetate, dydrogesterone, chlormadinone acetate, ethisterone, dimethisterone, norethisterone, norethisterone acetate, **norethisterone** enanthate, ethynodiol acetate, megestrol acetate and allylestrenol (column 2, lines 14-19). Estrogen and the luteal hormones are present in amounts of 0.01 to 10% and with the luteal hormone present in about 1 to 5 times that of the estrogen (column 2, lines 20-29). Tackifier is present in amount of 0-40% by weight of the total amount of the preparation (column 3, lines 36-45) while the softening agent is present in amounts of 10-70% by weight of the total preparation (column 3, line 13). One of the essential ingredients of the patch is a polymer base that is styrene-butadiene-styrene block copolymer or styrene-isoprene-styrene block copolymer (column 2, lines 30-43) in amounts of 20 to 90% (column 3, line 5).

In example 13, the styrene-isoprene-styrene block copolymer is 287, the liquid paraffin, which is a softener is 41% and rosin ester tackifier is 25%. In examples 15 and 16, the amount

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of styrene-isoprene-styrene block copolymer is 20 and 29% respectively, amount of the liquid paraffin softener is 33 and 30% respectively and the tackifier is 36 and 20% respectively. The amounts of estradiol in examples 13, 15 and 16 are 1%, 1% and 0.5% respectively and these amounts are not more than 25 by weight based on the total weight. These amounts meet the limitation amounts in instant claim 5.

Hirano meets the limitation of the claims.

6. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Hirano et al. (US 5,820,878).

The teachings in the disclosure of Hirano are discussed above. For the same reasons, Hirano meets the limitations of the claims under 35 USC 102(a).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

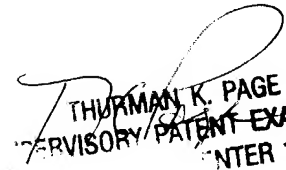
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
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THURMAN K. PAGE
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